NDA 19-0l2/S-024

OCT 2 2000

McNeil Consumer Healthcare
Attention: Paula Oliver
Senior Director, Regulatory Compliance
7050 Camp Hill Road
Fort Washington, PA 19034-2299

Dear Ms. Oliver:

Please refer to your supplemental new drug application dated January 17, 2000, received January 18, 2000, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Motrin IB Ibuprofen Gelcaps.

We acknowledge receipt of your submissions dated April 18, July 12, and August 8, 2000.

This supplemental new drug application provides for labeling in Drug Facts format for the 8-, 24-, 50-, and 100-count cartons/bottles of Motrin IB Gelcaps.

We have completed the review of this supplemental new drug application, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the draft labeling dated July 12, 2000. Accordingly, the supplemental new drug application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the draft labeling dated July 12, 2000, and must be formatted in accordance with the requirements of 21 CFR 201.66.

Please be reminded that the flag statement "See New Label" should be deleted after 6 months of marketing.

Please submit 20 paper copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. Alternatively, you may submit the FPL electronically according to the guidance for industry titled Providing Regulatory Submissions in Electronic Format NDAs (January 1999). For administrative purposes, this submission should be designated "FPL for approved supplement NDA 19-012/S-024." Approval of this submission by FDA is not required before the labeling is used.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Practitioner" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MED WATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 3l4.80 and 314.81.

If you have any questions regarding this application, please contact Thomas A. Parmelee, Pharm.D., Regulatory Project Manager, at (301) 827-2271.

Sincerely,

Linda M. Katz, M.D., M.P.H.
Deputy Director
Division of Over-the-Counter Drug Products
Office of Drug Evaluation V
Center for Drug Evaluation and Research

Drug Facts (continued)

Stop use and ask a doctor if

- an allergic reaction occurs. Seek medical help right away.
- pain gets worse or lasts more than 10 days
- fever gets worse or lasts more than 3 days
- stomach pain or upset gets worse or lasts
- redness or swelling is present in the painful area
- any new symptoms appear

If pregnant or breast-feeding, ask a health professional before use. It is especially important not to use ibuprofen during the last 3 months of pregnancy unless definitely directed to do so by a doctor because it may cause problems in the unborn child or complications during delivery.

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

Directions

- do not take more than directed

adults and children 12 years and older	■ take 1 gelcap every 4 to 6 hours while symptoms persist ■ if pain or fever does not respond to 1 gelcap, 2 gelcaps may be used, but do not exceed 6 gelcaps in 24 hours, unless directed by a doctor ■ the smallest effective dose should be used
children under 12 years	■ ask a doctor

Other information

- **do not use if neck wrap or foil inner seal imprinted "Safety Seal®" is broken or missing**
- store at 20 - 25°C (68 - 77°F)
- avoid high humidity and excessive heat above 40°C (104°F)
- see end panel for lot number and expiration date

See New Label

Motrin® IB

IBUPROFEN TABLETS USP, 200 mg

Pain Reliever/ Fever Reducer

100 COATED TABLETS

Gelcaps

See New Label

Motrin® IB

IBUPROFEN TABLETS USP, 200 mg

Pain Reliever/ Fever Reducer

100 COATED TABLETS

Gelcaps

Drug Facts (continued)

Inactive ingredients

benzyl alcohol, butylparaben, castor oil, cellulose, corn starch, edetate calcium disodium, FD&C Yellow #6, gelatin, hydroxypropyl methylcellulose, iron oxide, methylparaben, povidone, propylparaben, silicon dioxide, sodium lauryl sulfate, sodium propionate, sodium starch glycolate, titanium dioxide

Questions or comments?

Call toll-free 1-800-962-5357

McNeil Consumer Healthcare
DIVISION OF MCNEIL – PPC, INC.
FORT WASHINGTON, PA 19034 USA
 U.S. Patent No. 4,820,524

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Drug Facts

Active ingredient (in each gelcap) ***Purposes***

Ibuprofen 200 mg..... Pain reliever/fever reducer

Uses temporarily relieves minor aches and pains due to:

- headache
- muscular aches
- minor pain of arthritis
- toothache
- backache
- the common cold
- menstrual cramps
- reduces fever

Warnings

Allergy alert: Ibuprofen may cause a severe allergic reaction which may include:

- hives
- facial swelling
- asthma (wheezing)
- shock

Alcohol warning: If you consume 3 or more alcoholic drinks every day, ask your doctor whether you should take ibuprofen or other pain relievers/fever reducers. Ibuprofen may cause stomach bleeding.

Do not use if you have ever had an allergic reaction to any other pain reliever/fever reducer

Ask a doctor before use if you have

- stomach pain
- problems or serious side effects from taking pain relievers or fever reducers

Ask a doctor or pharmacist before use if you are

- under a doctor's care for any serious condition
- taking any other drug
- taking any other product that contains ibuprofen, or any other pain reliever/fever reducer

When using this product give with food or milk if stomach upset occurs